UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,875	04/05/2006	Jurgen Dorn	568-PDD-02-08-US-[57P]	7921

79990 7590 07/16/2010

C. R. Bard, Inc.
Bard Peripheral Vascular, Inc.
1415 W. 3rd Street
P.O. Box 1740
Tempe, AZ 85280-1740

EXAMINER	
WEBB, SARAH K	
ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
07/16/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,875	DORN ET AL.	
	Examiner	Art Unit	
	SARAH WEBB	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *27-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/24/10; 6/18/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 6/18/2010 have been fully considered but they are not persuasive. Applicant argues that Keegan does not disclose the catheter as claimed because it includes a junction piece (9) attached to primary catheter shaft (2) and sheath (4). Applicant also argues that the junction piece (9) is disclosed as being more flexible than the catheter shaft (2) and sheath (4), so it does not meet the claimed limitations of the "sleeve shaped member." As applicant points out, the junction piece (9) is adhered to the catheter body (2) and sheath (4) so that it forms a unitary device. For the purposes of this rejection, junction piece (9) is considered to be an integral part of the catheter body. Since all the components are combined to form a unitary device and include the claimed structures, it is irrelevant how the device is manufactured. Keegan is relied upon for showing the claimed structures, so the material properties of one component are irrelevant to the issue at hand. Therefore, the previous rejection has been maintained.

Information Disclosure Statement

2. The information disclosure statement filed 1/27/2010 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information

referred to therein has not been considered. Applicant requested consideration of DE19936059. An English translation was not provided, so the reference has not been considered.

Claim Objections

3. Claims 3, 4, 16, and 23 are objected to because of the following informalities: Claims 3 and 4 refer to "sleeve", but claim 1 calls out "sleeve shaped component." Claim 16 - "guider tube" should be changed to "guide tube." Claim 23 refers to 'the proximal exit port", but claim 1 calls out "proximal end opening." Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-9, 11, 12, and 15-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keegan et al. (US 2003/0109886) in view of Carter (US 6,663,614).

Keegan discloses a trans-luminal, guidewire-advanced, rapid-exchange surgical delivery device having a proximal end, a primary shaft (2) and a distal zone to be advanced over the guidewire along a bodily lumen to a site of surgery; and characterized by:

a guidewire lumen lying to one side of the primary shaft (2) and a proximal end opening (11) which lies to one side of the shaft, wherein the guidewire lumen extends distally beyond the end of the primary shaft;

a sleeve shaped means (4) for defining a lumen to receive a surgical element distal of the tubular means, the sleeve shaped means having a braided reinforcing filamentary material within the wall thickness of the sleeve (paragraph 119), wherein the braided material stops short of the distal end of the sleeve, and having a proximal end which is form- fitted over the primary shaft and has a radially inwardly tapering portion (9) proximal end, said inwardly tapering portion defining a proximal guidewire lumen exit port (11).

Keegan fails to disclose a tubular means for a guidewire and for defining a guidewire lumen, the tubular means including a guide tube. Carter discloses a lubricious liner (48) provided on the walls of a lumen to facilitate advancement a guidewire within a lumen (col. 7, In. 1-10). It would have been obvious to one of ordinary skill in the art to modify the guidewire lumen of Keegan et al. to provide a lubricious liner or "guide tube" on the walls of the guidewire lumen (including the distal funnel portion 12) in order to reduce friction between the walls of the lumen and the guidewire and to facilitate advancement of the device over the guidewire as suggested by Carter.

Regarding claims 2 and 3, Keegan discloses said primary shaft (2) is a tube, said tube contains an inner shaft (3) which, in use, may slide relative to the tube, whereby the imposition of endwise compression on the inner shaft and endwise tension

on the tube may withdraw the sleeve proximally relative to the distal end of the inner shaft.

Regarding claim 4, Keegan discloses the distal end of the inner shaft (3) is configured as a pusher, to maintain the position of said surgical element at said site of surgery during proximal withdrawal of the sleeve to expose the surgical element to the bodily lumen (paragraph 151).

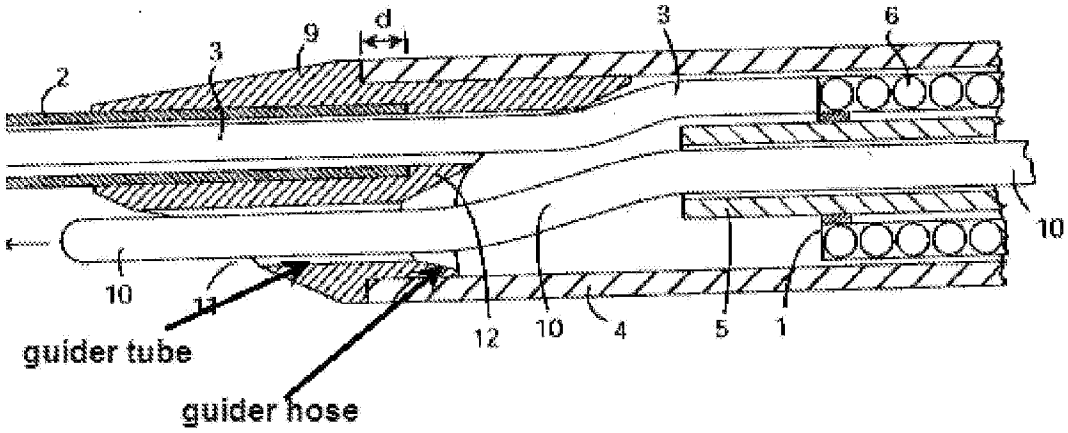
Regarding claims 5 and 6, Keegan et al. disclose the device includes the surgical element, wherein the surgical element is a self- expanding stent (7; paragraph 118).

Regarding claim 11, the claimed phrase "form-fitted by the application of heat and radially inward pressure" is being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. See MPEP 2113.

Regarding claim 12, Keegan et al. disclose the sleeve includes a push zone through which an endwise compression force imposed on the proximal end of the primary shaft can be transferred to the sleeve for advancing the sleeve along the bodily lumen to the site of surgery. Regarding claim 15, Keegan et al. disclose the push zone is found immediately distal of the distal end of the primary shaft.

Regarding claim 17, Keegan et al. modified by Carter disclose a guidewire guider hose (lubricious liner of the distal funnel portion of the guidewire lumen, see figure

below) having a proximal end and a distal end, said proximal end being contiguous with the distal end of the guider tube.



Regarding claim 18, Keegan modified by Carter discloses the distal end of the guider hose (see figure above) is flared radially outwardly, towards the luminal wall of the sleeve (Fig. 2, 3).

Regarding claim 19, Keegan modified by Carter discloses wherein the inner shaft (2) extends distally beyond the distal end of the guider hose, along a path between the abluminal wall of the guider hose and the luminal wall of the sleeve (Fig. 2G).

Regarding claim 20, Keegan et al. modified by Carter disclose the distal end of the inner shaft (3) carries an annular surgical element pusher (6) which defines a portion of the length of the guidewire lumen which is aligned with the lumen for the guidewire beyond the distal end of the guider hose (Fig. 2G).

Regarding claim 21, Keegan et al. disclose the annular pusher (6) carries a carrier tube (5) which extends distally from the annular pusher and itself defines a portion of the length of the guidewire lumen (Fig. 2G).

Regarding claim 22, Keegan et al. disclose the carrier tube (5) carries a radiopaque marker (13) band at or near its distal end (paragraph 128; Fig. 3E).

Regarding claim 23, Keegan et al. modified by Carter disclose the carrier tube (5) extends proximally from the annular pusher (6), but fail to disclose the carrier tube tapers outwardly towards the luminal wall of the sleeve. Keegan et al. disclose the funnel portion (12), which tapers outwardly toward the wall of the sleeve, assists in guiding the guidewire into the narrower guidewire lumen (paragraph 133). It would have been obvious to modify the carrier tube to also include a funnel portion which tapers outwardly towards the luminal wall of the sleeve in order to assist in guiding the guidewire into the carrier tube so that the guidewire can easily be inserted through the proximal guidewire port if desired.

Regarding claim 24, Keegan et al. modified by Carter discloses the inner shaft (130) is connected to the annular pusher between the distal end of the primary shaft and the annular pusher, said connector permitting adjustment of the axial position of the annular pusher (6) relative to the distal end of the sleeve (4), during assembly of the device, to cater for different lengths of the surgical element. The position of the pusher (6) relative to the sleeve may be adjusted by axial movement provided to the annular pusher through its connection to the inner shaft (Fig. 26).

Regarding claim 25, Keegan et al. modified by Carter discloses the inner shaft (3) comprises a distal portion of solid cross-section (131) and a proximal tube portion (130), the tubular portion extending within the primary tube shaft and distally therefrom, to said connector, or to a point proximal of said connector (Fig. 26).

Regarding claim 26, Keegan et al. modified by Carter discloses the inner shaft exhibits an unbroken metal strand as far as the annular pusher (Fig. 26).

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keegan et al. (US 2003/0109886) in view of Carter (US 6,663,614) as applied to claim 1 above, and further in view of Betelia et al. (US 6,945,989).

Keegan fails to disclose the distal end of the sleeve (4) is tapered inwardly to provide the device, at least prior to its arrival at the site of surgery, with a more or less atraumatic tip. Betelia et al. disclose stent delivery catheter for deploying a self expanding stent, wherein the stent delivery catheter comprises an outer sheath having a distal tip (18) which is tapered inwardly to provide an atraumatic tip (Fig 1 B; col. 5, In. 65 - col. 6, In. 9). Betelia et al. discloses the tapered outer sheath is advantageous over a conical or tapered nosepiece on the inner shaft, such as the nosepiece disclosed by Keegan et al, because the nosepieces risk catching on the wall of the blood vessel and/or dislodging embolic material (col. 2, In. 4-22). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Keegan et al. to provide a tapered outer sheath rather than a tapered nosepiece as suggested by Betelia et al. in order to facilitate advancement of the sheath with minimal risk of dislodging embolic material or causing injury to the vessel.

6. Claim 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keegan et al. (US 2003/0109886) in view of Carter (US 6,663,614) as applied to claim 1 above, and further in view of Roberts et al. (US 5,603,698).

Keegan modified by Carter fail to disclose the push zone corresponds to an annulus in which the sleeve has a reduced outside diameter relative to its diameter immediately proximal of said push zone and reduced inside diameter relative to its inside diameter immediately proximal of said push zone. Roberts et al. disclose a self expanding stent delivery catheter having a sheath (20) with a reduced diameter portion (24; Fig. 1). Roberts et al. discloses that providing an outer sheath having diameters which conform to closely to the diameter of the inner components enhances flexibility and reduces kinking for easier navigation through vessels (col. 5, In. 14-44). It would have been obvious to one of ordinary skill in the art to decrease inner and outer diameters of the of the sheath in the region distal the primary shaft due to the reduced diameter of the inner components in that region in order to enhance flexibility and reduce kinking as suggested by Roberts et al.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAH WEBB whose telephone number is (571) 272-5749. The examiner can normally be reached on 9:00am - 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SARAH WEBB/
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
6/30/10